

I. Status of the Application

Claims 1-20 are pending. The Examiner restricted the application, under 35 U.S.C. §121, to one of the ten groups described below.

II. The Invention

5 The present invention is directed generally to novel receptors related to cytokine receptors (e.g., primate or rodent), cytokine receptor like molecular structures (designated DNAX Interferon-like Receptor Subunits: DIRS), and their biological activities. Applicants teach two different DIRS receptor subunits (designated DIRS1 and DIRS2), nucleic acids encoding them, and methods for their
10 production and use.

III. The Restriction Requirement

 The Examiner restricted the application into the following ten groups: (Note, Group X was inadvertently mislabeled in Paper No. 6. It was erroneously listed as being directed to DIRS1. It should be directed to DIRS2. To avoid future confusion,
15 Applicants respectfully request correction.)

- I. Claims 1-6, directed generally to DIRS1 polypeptides, variants thereof, and to kits and compositions thereto, classified in Class 530, Subclasses 351;
- II. Claims 1-6, directed generally to DIRS2 polypeptides, variants thereof, and to kits and compositions thereto, classified in Class 530, Subclasses 351;
- 20 III. Claims 12-18, directed generally to polynucleotides encoding DIRS1 polypeptides, DIRS1 fusion proteins, and to kits and compositions thereto, classified in Class 536, Subclass 23.5;
- IV. Claims 12-18, directed generally to polynucleotides encoding DIRS2 polypeptides, DIRS2 fusion proteins, and to kits and compositions thereto,
25 classified in Class 536, Subclass 23.5;
- V. Claim 19 directed generally to a method of modulating the physiology or development of a cell or tissue culture cells comprising exposing said cell to an agonist or antagonist of a DIRS1 protein, Class and Subclasses indeterminate;
- 30 VI. Claim 19 directed generally to a method of modulating the physiology or development of a cell or tissue culture cells comprising exposing said cell to

an agonist or antagonist of a DIRS2 protein, Class and Subclasses
indeterminable;

VII. Claim 20 directed generally to a method of modulating the physiology or
development of a cell or tissue culture cells comprising exposing said cell with
5 a polynucleotide encoding a DIRS1 polypeptide and another cytokine
receptor subunit, classified in Class 435 and Subclass 6;

VIII. Claim 20 directed generally to a method of modulating the physiology or
development of a cell or tissue culture cells comprising exposing said cell with
10 a polynucleotide encoding a DIRS2 polypeptide and another cytokine
receptor subunit, classified in Class 435 and Subclass 6;

IX. Claims 7-11 directed generally to a binding composition, e.g., an antibody, to
a DIRS1 protein, a kit comprising said binding composition, a method of
purifying said DIRS1 protein using said binding composition, and a
therapeutic composition comprising said binding composition with a carrier
15 classified in Classes 530, Subclass 387.1; or

X. Claims 7-11 directed generally to a binding composition, e.g., an antibody, to
a DIRS2 protein, a kit comprising said binding composition, a method of
purifying said DIRS2 protein using said binding composition, and a
therapeutic composition comprising said binding composition with a carrier
20 classified in Classes 530, Subclass 387.1.

IV. Response to Restriction Requirement

Applicants provisionally elect, with traverse, Group III (Claims 12-18) directed
generally to polynucleotides encoding DIRS1 polypeptides, DIRS1 fusion proteins,
and to kits and compositions thereto, classified in Class 536, Subclass 23.5.

25 Applicants understand that there are two criteria for a proper Restriction
Requirement according to MPEP §803:

- (1) the invention must be independent or distinct as claimed, and
- (2) there must be a serious burden on the Examiner if the restriction is not
required.

30 Moreover,

"If the search and examination of the entire application can be made without
serious burden, the examiner must examine it on the merits, even though it
includes claims to independent or distinct inventions."

Also,

"Where plural inventions are capable of being viewed as related in two ways, both applicable criteria for distinctness must be demonstrated to support a restriction requirement."

5 The restriction requirement is believed to be improper since the claims of Groups I, III, and IX are so closely related they should remain joined to preserve the unity of the invention. Furthermore, their examination together would not present a serious burden to the Examiner. The claims of the invention relate to a single subject matter. Restriction must then be based upon their distinctness, as claimed.

10 According to MPEP §802.01, this means that they are capable of separate manufacture, use, or sale, and are patentable over each other. The Examiner has alleged that examination would *prima facie* present a serious burden but, determination of that burden has not been stated for the record. Applicants respectfully request reconsideration of this determination and a statement, for the
15 record, that examination of the groups together would, in fact, be a serious burden.

 The polynucleotides of Group III, the polypeptides of Group I, and the binding compositions, e.g., antibodies, of Group IX are related to each other since they can be used in one method because they have independent utility that can be exchanged.

20 The DIRS1 polypeptides of Group I, the DIRS1 polynucleotides of Group III, and the DIRS1 antibodies of Group IX can be used in combination with each other for a common use, e.g., to identify particular cells in a biological sample.

 Specifically, the Group IX antibodies and Group I polypeptides can be used in concert with the Group III polynucleotides to screen for dendritic cells; by selectively
25 sorting dendritic cells in a biological sample from other immune cells using a DIRS1 protein signature of Group I as a selective marker. Thus, putative dendritic cells could easily be identified in a screening assay based on their expression of the DIRS1 receptor, e.g., in a FACS sorter using an antibody that selectively binds DIRS1.

 Subsequent confirmation of the dendritic identity of a suspected cell could be
30 obtained by subjecting a portion of the FACS sorted cells to hybridization with a DIRS1 nucleic acid of Group III. This two-part selection would be an invaluable method of producing high quality dendritic cells from a sample of mixed cell types. As such, the method requires maintaining a DIRS1 nucleic acid with its cognate DIRS1 protein and antibody. Accordingly, the inventions of Groups I, III, and IX
35 should remain joined since they have similar utility. A similar argument exists to maintain the groups directed to DIRS2 polypeptides, polynucleotides, and antibodies

(i.e., Groups II, IV, and X). Also, the class/subclass for each of Groups I and II; III and IV; VII and VIII; and, IX and X; are the same.

Furthermore, according to MPEP §821.04,

5 "if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined."

The MPEP at §821.04 further instructs that,

10 "applicants are encouraged to present such process claims. . . in the application at an early stage of prosecution."

Accordingly, before allowance of the subject matter of the Group III claims (DIRS1 polynucleotides of Claims 12-18), Applicants intend to present additional claims directed generally to methods of making and using DIRS1 polynucleotides
15 e.g., methods of hybridization using DIRS1; methods of detecting DIRS1; methods of transforming a cell with DIRS1 polynucleotides; methods of generating an antibody using the DIRS1 polynucleotides, etc. Specifically, Applicants intend to submit claims in a form that will make examination more effective, streamlined, and hopefully lead to early allowance.

20 When the restriction is finalized, Applicants will address the issue of inventorship for the selected claims and, if necessary, amend the inventorship accordingly.

V. Response to the Notice to Comply

Applicants filed a separate response to the "Notice to Comply" dated
25 27-APR-00 (Paper No. 6), which accompanied the present restriction request. Applicants mailed their sequence response (including: (1) a substitute paper and write-protected computer readable copy of the Sequence Listing as required under 37 CFR §1.825(d); (2) a statement under 37 CFR §1.825(d) and (3) a copy of the "Error Report") directly to "Box Sequence" on the same day the present restriction
30 response was mailed.

Summary

Applicants elect Group III for examination (Claims 11-18). This election and response to the latest communication is believed to be a good faith, fully responsive, and substantially complete reply, which is designed to advance prosecution of the
35 present application. Should there be any question regarding the sufficiency of this

submission, Applicants respectfully request notification of any inadvertent deficiencies and an opportunity to remedy them under 37 CFR §1.135(c).

Claims 11-18 clearly and patentably define the invention. Applicants respectfully request the Examiner to substantively examine and pass the claims to allowance at the earliest possible date. Should this be deemed inappropriate, Applicants respectfully request the Examiner grant an interview with Applicants' representative to discuss any outstanding issues. The Examiner is invited to telephone the undersigned at (650) 496-1244 to arrange for a mutually convenient time and form for the interview.

Respectfully submitted,



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